UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 15, 2024

ANEBULO PHARMACEUTICALS, INC
(Exact name of Registrant as Specified in Its Charter)

Delaware	001-40388	85-1170950
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

Anebulo Pharmaceuticals, Inc. 1017 Ranch Road 620 South, Suite 107 Lakeway, TX	78734
(Address of Principal Executive Offices)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (512) 598-0931

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.0.001 par value per share	ANEB	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2024, Anebulo Pharmaceuticals, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended March 31, 2024 and providing a business update. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description

99.1	Press Release dated May 15, 2024
104	Cover Page of Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ANEBULO PHARMACEUTICALS, INC.

Date: May 15, 2024

By: */s/ Richard Anthony Cunningham*
Richard Anthony Cunningham
Chief Executive Officer (*Principal Executive Officer*)

Exhibit 99.1

Anebulo Pharmaceuticals Reports Third Quarter Fiscal Year 2024 Financial Results and Recent Updates

AUSTIN, Texas (May 15, 2024) – Anebulo Pharmaceuticals, Inc. (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid toxicities that include acute cannabinoid intoxication (ACI) and unintentional cannabis poisoning (the "Company" or "Anebulo"), today announced financial results for the three months ended March 31, 2024, and recent updates.

Third Quarter Fiscal Year 2024 and Subsequent Highlights:

- Anebulo prioritizes development of selonabant IV formulation for unintentional cannabis poisoning in children in response to the growing medical need and impending change in DEA scheduling
- On April 30, 2024, the United States Department of Justice announced plans to reduce restrictions and reclassify marijuana as a less dangerous drug
- Pediatric patients accidentally exposed to cannabis are at risk of serious and life-threatening outcomes including Central Nervous System (CNS) depression, seizures, and coma

"The recent decision by the United States Department of Justice to support rescheduling of marijuana from a schedule I to a schedule III controlled substance, is a move we believe will ultimately lead to increased use of cannabis containing products among US households. This potentially includes edible products that are often the cause of unintentional cannabis poisoning in children. Our decision to prioritize the development of an intravenous treatment for children is driven by multiple factors. Our prior discussions with United States Food and Drug Administration have highlighted the need for an alternative formulation of selonabant for treating younger patients. There is increasing recognition among clinicians that this is a growing unmet medical need in a vulnerable population where there are no approved treatments. Our belief is that the path to approval for an oral treatment for adult ACI may be facilitated by an initial approval in the pediatric population," commented Richie Cunningham, Chief Executive Officer of Anebulo.

"Anebulo is uniquely positioned to provide a rapid and clinically impactful solution for Emergency Departments to treat children suffering from unintentional cannabis poisoning," Cunningham continued. "Research has shown children are much more sensitive to the toxic effects of cannabis. Key factors such as smaller body size, reduced ability to metabolize delta-9-tetrahydrocannabinol (THC), and the fact that younger children have an underdeveloped endocannabinoid system with more cannabinoid receptor type 1 (CB1) receptors in the brain all contribute to a much greater risk to children.

"The risk is also evident in how cannabis effects this population; in contrast to adults who are exposed to acute cannabis toxicity, children who unintentionally consume edible cannabis products are at greater risk of more serious and life-threatening outcomes such as CNS depression, respiratory depression, seizures, and coma. Recent headlines from the Wall Street Journal and other major media outlets have highlighted the issue. We find ourselves at a moment where the tailwinds and support for a treatment for this population are real and evident, which supports the rationale to prioritize our selonabant IV formulation for the most vulnerable patients in need of a treatment that has the potential to quickly reverse the effects of THC.

"ACI in adults continues to be a major market opportunity for selonabant. However, we have evaluated the potential advantages of prioritizing a near term solution for children with more serious symptoms over progressing our plans for an adult ACI treatment and have decided to focus current efforts on the pediatric indication at this time, which we believe offers the potential for a faster timeline to approval relative to the adult oral product. We believe the incidence of unintentional cannabis poisoning in children presenting to the emergency department is rare, with less than 50,000 cases per year. Importantly, America's Poison Centers have also reported significant annual increases in the number of pediatric cases reported in recent years and that number continues to grow.

"In response to this growing unmet medical need, our intravenous formulation of selonabant is currently being scaled up for initial clinical safety studies."

Financial Results for the three months ended March 31, 2024

- Operating expenses in the third quarter of fiscal 2024 were $1.7 million compared with $2.9 million in the same period in fiscal 2023.
- Net loss in the third quarter of fiscal 2024 was $1.7 million, or $(0.06) per share, compared with a net loss of $2.8 million, or $(0.11) per share, in the third quarter of fiscal 2023.
- Cash and cash equivalents were $5.1 million as of March 31, 2024.

About Selonabant (ANEB-001)

Our lead product candidate is selonabant (ANEB-001), a potent, small molecule antagonist of CB1, under development to address the unmet medical need for a specific antidote for cannabis toxicity, including ACI and unintentional cannabis poisoning. Selonabant is an orally bioavailable, readily absorbed treatment candidate that we anticipate will rapidly reverse key symptoms of ACI. Selonabant is also under development as a parenteral treatment for unintentional cannabis poisoning. Selonabant is protected by two issued patents covering various methods of use of the compound and composition of matter of the crystalline form of selonabant. We also have multiple pending applications covering various methods of use of the compound and delivery systems. An observational study in patients presenting to Emergency Departments with ACI is currently ongoing. The study will determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected subjective assessments.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication, unintentional cannabis intoxication and, longer term, for substance use disorders. Its lead product candidate, selonabant, has completed dosing in a Phase 2 clinical trial

(www.clinicaltrials.gov/ct2/show/NCT05282797) evaluating its utility in blocking and reversing the negative effects of acute cannabinoid intoxication. Selonabant is a competitive antagonist at the human CB1. For further information about Anebulo, please visit www.anebulo.com.

Forward-Looking Statements

Statements contained in this press release that are not statements of historical fact are forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these forward-looking statements can be identified by words such as "anticipate," "designed," "expect," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: plans by the United States Department of Justice to reduce restrictions and reclassify marijuana as a less dangerous drug; the decision to support rescheduling of marijuana from a schedule I to a schedule III controlled substance ultimately leading to increased use of cannabis containing products among US households including edible products that are often the cause of unintentional cannabis poisoning in children; the path to approval for an oral treatment for adult ACI being facilitated by an initial approval in the pediatric population; being uniquely positioned to provide a rapid and clinically impactful solution for Emergency Departments to treat children suffering from unintentional cannabis poisoning; the tailwinds and support for a treatment supporting the rationale to prioritize the advancement of a selonabant IV formulation for the most vulnerable patients; the treatment having the potential to quickly reverse the effects of THC; a pediatric indication offering the potential for a faster timeline to approval relative to the adult oral product; the incidence of unintentional cannabis poisoning in children presenting to the emergency department being rare; and scaling up an intravenous formulation of selonabant for initial clinical safety studies. .. You are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: our ability to pursue our regulatory strategy, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of our product candidates in the marketplace and the successful development, marketing or sale of our products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate and our ability to retain our key employees or maintain our Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statements included in our Annual Report on Form 10-K for the year ended June 30, 2023, and our subsequent filings with the SEC, including subsequent periodic reports on Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. All forward-looking statements made in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Except as required by law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect new information, future events, changed conditions or otherwise after the date of this press release.

CONTACTS:

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Daniel George
Acting Chief Financial Officer
(512) 598-0931
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Condensed Balance Sheets

	March 31, 2024	June 30, 2023
Cash and cash equivalents	$ 5,147,139	$ 11,247,403
Total assets	5,995,635	11,670,151
Total liabilities	1,010,321	1,068,801
Total stockholders' equity	4,985,314	10,601,350

Condensed Statements of Operations

	Three Months Ended March 31,	
	2024	2023
Research and development	$ 748,339	$ 1,089,342
General and administrative	915,912	1,774,699
Total operating expenses	1,664,251	2,864,041
Loss from operations	(1,664,251)	(2,864,041)
Other (income) expenses:		
Interest expense	59,696	-
Interest income	(68,084)	(79,152)
Other	(2,321)	13,082
Total other income, net	(10,709)	(66,070)
Net loss	$ (1,653,542)	$ (2,797,971)
Weighted average common shares outstanding, basic and diluted	25,933,217	25,633,217
Net loss per share, basic and diluted	$ (0.06)	$ (0.11)